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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,238	02/03/2006	Carlos Matute Almu	P4043-258	2543
2352 7590 03/02/2010 OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403				
EXAMINER				
CRUZ, KATHLEEN ANN				
ART UNIT		PAPER NUMBER		
1628				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,238

Applicant(s)

MATUTE ALMAU ET AL.

Examiner

KATHRIEN CRUZ

Art Unit

1628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/22)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Claims 1-6 are pending.

Applicants response filed November 25, 2009 has been received and entered in the application.

Priority

This application is a nation stage entry of PCT/ES04/00361 (dated 08/04/2004) which claims benefit of foreign priority P200301853 (dated 08/04/2003).

Action Summary

Claim 3 is rejected under 35 U.S.C. 112, second paragraph is withdrawn.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neely (WO 99/38532) of record and Smith (The P2X7 purinergic receptor on bovine macrophages mediates mycobacterial death, Veterinary Immunology and Immunopathology, 78, 2001, pg 249-262) is withdrawn.

However, due to applicant's amendment of claims a new rejection is made below.

Response to Arguments

Applicants argue that Neely reference does not disclose the use of o-ATP as a P2X antagonist. This argument has been fully considered but has not been found persuasive. Neely clearly teaches that a method of inhibiting fibrosis and/or sclerosis in

a subject afflicted with a fibrosing or sclerosing disorder by administering an amount of P2X purinoceptor antagonist (page 4, lines 14-17). Therefore, Neely does teach the use of o-ATP as a P2X antagonist.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (The P2X7 purinergic receptor on bovine macrophages mediates mycobacterial death, Veterinary Immunology and Immunopathology, 78, 2001, pg 249-262).

Smith teaches that P2X7 is an ionotropic ATP gated channel that plays a role in a variety of immune response (page 249, introduction) and an important effector pathway in the immune response (page 260, first paragraph). Smith teaches that o-ATP and KN-62 are P2X7 purinergic receptor antagonist (page 260, first paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (The P2X7 purinergic receptor on bovine macrophages mediates mycobacterial death, *Veterinary Immunology and Immunopathology*, 78, 2001, pg 249-262) of record as applied to claims 1-2 above, and further in view of Neely (WO 99/38532) of record and Jameson et al (U.S. Patent 5,589,458).

Smith as cited above.

Smith does not expressly teach the treatment of multiple sclerosis.

Neely teaches a method of inhibiting fibrosis and/or sclerosis in a subject afflicted with a fibrosing or sclerosing disorder by administering an amount of P2X purinoceptor antagonist (page 4, lines 14-17). Neely teaches that sclerosis are muscular function loss cause by increase fibrosis (page 8, lines 19-20).

Jameson teaches that autoimmune diseases are characterized as an immune reaction against "self" antigens. Autoimmune diseases include systemic lupus

erythematosus (SLE), rheumatoid arthritis (RA) and **multiple sclerosis (MS)** (column 1, lines 22-25).

It would have been obvious to one of ordinary skills in the art at the time of the invention to treat an autoimmune disease such as multiple sclerosis. One would have been motivated to treat of autoimmune disease such as multiple sclerosis because o-ATP is an important effector pathway in the immune response as taught by Smith and P2X purinoceptor antagonist are useful in the treatment of fibrosis and/or sclerosis as taught by Neely. Additionally, it is known in the art that multiple sclerosis is an autoimmune disease as taught by Jameson.

For these reasons, the claimed subject matter is deemed to fail to be patentably distinguishable over the state of the art as represented by the cited reference. The claims are therefore, properly rejected under 35 U.S.C. 103. In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

Claims 1-6 are rejected.

No claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1617

/San-ming Hui/

Primary Examiner, Art Unit 1628